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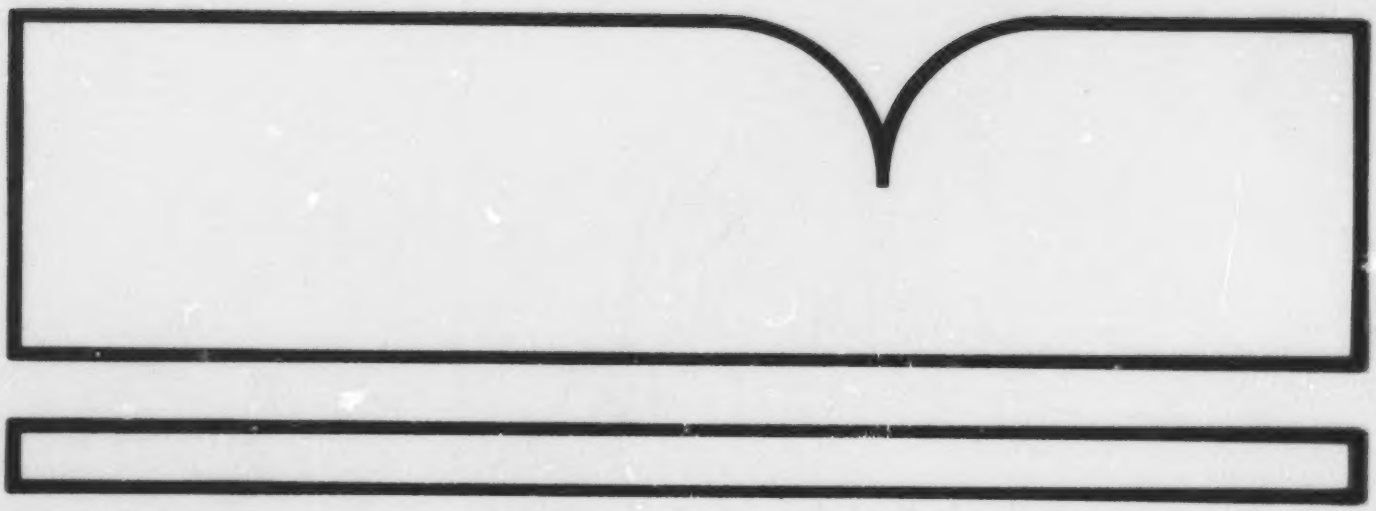
Guidance for the Reregistration of Pesticide Products Containing Fenaminosulf as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Sep 83



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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING AS THE ACTIVE INGREDIENT

FENAMINOSULF
(034201)

CASE NUMBER 359B

CAS 140-56-7

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

September 1983

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION

A. Introduction

This Registration Standand presents the regulatory position of the Environmental Protection Agency (the Agency) on registration of manufacturing-use products (MPs) containing the fungicide Fenaminosulf (p-(dimethylamino)benzenediazo sodium sulfonate). The Agency's position is based on a consideration of available data for all currently registered uses and registered MPs with Fenaminosulf as the sole active ingredient. Registration requests for products containing Fenaminosulf will be evaluated based on this Standard.

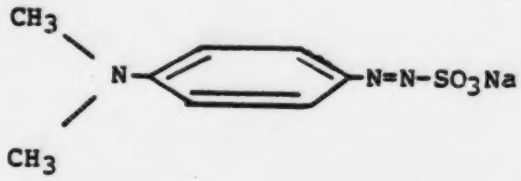
The Standard considers labeling requirements, tolerances, "Special Local Need" registrations authorized by FIFRA Section 24(c), as well as Federal Registrations granted or pending under FIFRA Section 3. Finally, the Agency sets forth the data requirements that must be met to register and reregister products covered by this document.

There is currently one (1) registered manufacturing-use product consisting of the technical grade of Fenaminosulf (80%) and seven (7) registered end-use products containing Fenaminosulf as the sole active ingredient. There are also seven (7) products containing Fenaminosulf in combination with other pesticides. In addition, there is one (1) FIFRA Section 24(c) "Special Local Need" registration.

B. Description of the Chemical and Use Profile

Fenaminosulf is the International Organization for Standardization (ISO) and British Standards Institution (BSI) approved common name for p-(dimethylamino)benzenediazo sodium sulfonate. Other names include: Lesan, Dexon, Bayer 22555, Bayer 5072, diazoben, and sodium [4-(dimethylamino) phenyl]diazenesulfonate. The Chemical Abstracts Service (CAS) Registry Number is 140-56-7. The Office of Pesticides Programs (OPP) Internal Control Number (EPA Shaughnessy Number) is 034201.

The structural formula is:



Fenaminosulf is a yellowish-brown, odorless powder. The empirical formula is $C_8H_{10}N_3NaO_3S$. The solubility of Fenaminosulf in water is 2-3% at 25°C.

Mobay Chemical Corporation is the only registrant of technical Fenaminosulf. Fenaminosulf has been registered by the U.S.E.P.A. as a seed treatment fungicide for corn, cotton, cucumber, lima beans, peas, snap beans, sorghum, spinach, sugar beets, and table beets, and as seed piece treatments for sugar cane and pineapples. It is also used as a soil treatment fungicide for avocados, ornamentals, sugarcane seed beds, and for foliar application to lawns, orna-

mentals, and turf.

Fenaminosulf may be formulated with the fungicides PCNB (pentachloronitrobenzene), chlorothalonil, or with fertilizer. Single active ingredient formulations consist of 0.4% and 5% granular (G), 35% and 70% Wettable powder/dust (WP/D), and 70% WP. These formulations may be used as protective seed and seed piece treatments applied as a soil drench, a soil incorporation treatment, or as a foliar spray for turf and lawns. As a seed treatment, Fenaminosulf may be applied dry or as a slurry.

C. Regulatory Position

Based on a review and evaluation of all available data and other relevant information on Fenaminosulf, the Agency has made the following determinations:

1. Manufacturing-use products containing Fenaminosulf as the sole active ingredient may be registered for sale, distribution, and reformulation into end-use products, and for use, subject to the terms and conditions specified in this standard.

2. Registrants must provide or agree to develop additional data, as specified in Table A and Table B of this Standard, in order to maintain existing registrations or to obtain new product registrations.

3. The Agency has determined that the data supporting Fenamino-

sulf does not meet the Agency's present requirements. Due to the inadequacy of the data, there are extensive data gaps for Fenaminosulf.

4. Fenaminosulf is structurally related to azo dyes that are known to be carcinogenic. Studies submitted indicate that Fenaminosulf a mutagen. These facts establish the urgency to obtain a complete data base for this chemical in order to determine whether additional regulatory action is necessary.

5. The chemical is considered highly toxic to birds but moderately toxic to fish and aquatic invertebrates.

6. Radiolabeled C^{14} uptake studies must be performed with plants and animals to determine the metabolic routes and residues of concern. Additional plant and animal studies may be required to support any needed tolerances.

7. If tolerances need to be established, then adequate enforcement methods are required.

8. Data to support the establishment of reentry protection standards are not required because the Agency has determined based on the use patterns for Fenaminosulf, that the criteria in §158.140 are not met. However, due to concerns indicated in items 4 and 6 above, the Agency may reconsider the reentry question at a later date.

D. Regulatory Rationale

The Agency has determined that it will continue to allow the registration of products containing fenaminosulf, after consideration of the following:

1. The Agency does not have adequate data to conclude that Fenaminosulf is or is not an oncogenic agent. Two oncogenic studies submitted to date have been conducted with a formulation and are inadequate by the Agency's current standards. A third oncogenic study was conducted 34 years ago, under unknown experimental conditions, using one level of Fenaminosulf (synthesized in the laboratory and not characterized for purity). The Agency must wait for acceptable studies before reaching a decision. The Agency has no information that indicates continued use will result in any unreasonable adverse effects to man or his environment during the time data are being developed.

2. In the past, Fenaminosulf seed treatments have been considered non-food uses, therefore, no tolerances have been established for residues in or on any crop or animal product. The Agency's current position is that seed treatments are considered food use and, as such, require tolerances unless data is submitted showing no uptake of the chemical or the chemicals' degradates in the plant. Metabolic studies are needed to determine the residues of concern. When these residues have been identified and quantified, then it can be established whether or not tolerances, if needed,

should be expressed in terms of solely the parent compound per se or in terms of the parent and metabolites of toxicologicol concern. If plant metabolism and residue studies indicate that residues of Fenaminosulf will occcur in animal feed items, then animal metabolism studies may be needed. The need for animal feeding studies will depend on the results of the animal metabolism studies and the magnitude of the total Fenaminosulf residues in or on the feed items.

3. Since there are no established tolerances, no theoretical maximum residue concentration (TMRC) figures are possible at this time. If tolerances are established in the future, then dietary uptake figures will be computed.

4. Based on the submitted acute animal toxicity data, the Agency tentatively concluded that the dermal toxicity of technical Fenaminosulf is highly toxic (Category I); moderately toxic by oral ingestion (Toxicity Category II); and moderately toxic by inhalation (Category II). The Agency has no data on eye irritation or skin irritation.

5. No human toxicological hazards of concern to this Agency, other than mutagenicity, have been identified in studies reviewed for this Standard. However, most of the toxicology studies reviewed are not adequate to meet current data requirements.

6. Based on limited data, Fenaminosulf appears to degrade with

a half-life of 2 days in non-sterile soils. It also appears to be mobile in soils with low organic matter. However, these studies are not adequate to reach a final conclusion about the fate of Fenaminosulf in the environment or the exposure potential of the chemical to humans and wildlife.

7. It is not the Agency's policy to cancel or withhold registration merely because data are missing or inadequate (see FIFRA Sections 3(c)(2)(B) and 3(c)(7)). Rather, publication of this Standard provides a mechanism for identifying; 1) data needs, 2) registration requirements under the standard; and 3) allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received, and the Agency will determine, at that time, if the new data will affect the registration(s) of Fenaminosulf.

E. Criteria for Registration under this Standard

To be covered by this standard, products must contain Fenaminosulf as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use-pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described herein. These include making a commitment to fill

data gaps on a schedule specified by the Agency. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products (MP) must contain Fenaminosulf as the sole active ingredient. Each MP formulation proposed for registration must be fully described and include an appropriate certification of limits for all contaminants and impurities, and carry-over starting materials and/or intermediates above the level of 0.1% in the technical products.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MPs containing Fenaminosulf for any acute toxicity category, provided that the labeling of those products bears appropriate precautionary statements. Due to insufficiency of data, classification of Fenaminosulf cannot be made until the appropriate data is submitted and reviewed.

3. Use Patterns

To be registered under this Standard manufacturing-use products

containing Fenaminosulf may be labeled for formulation only into end-use products for:

•Terrestrial, food use on: (seed and seed piece treatments, as stated earlier in this Standard, are considered food uses until proven otherwise) pineapple, cucumbers, spinach, lima beans, snap beans, sugarcane (seed piece and seed beds), beets, corn, peas, sugar beets, avocados (soil treatment under avocado trees), cotton, and sorghum.

•Terrestrial, non-food use on: ornamental flowering plants, ornamental bulbs, ornamental turf, ornamental lawns, woody shrubs, ornamental woody shrubs, ornamental and/or shade trees, and ornamental vines.

•Greenhouse, non-food use on: ornamental flowering plants, flowering plants, ornamental woody shrubs.

•Domestic outdoor, non-food use on: soil treatment for ornamental flowering plants, shrubs, shade trees, bulb, and foliar application turf, and lawns.

G. REQUIRED LABELING

All manufacturing-use products containing Fenaminosulf must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specified information regarding label requirements.

1. Use Pattern Statements

The ingredient statement for MPs must list the active ingredient as:

Fenaminosulf, (p-(dimethylamino)benzenediazo sodium sulfonate)....._____%

In addition, all MPs must state that they are intended only for formulation into end-use products for the use patterns listed above. They must specify specific sites listed in Use Patterns in Section F.3 of the Standard. A limiting factor will be the data that supports these use patterns. No use may be included on the label, or labeling, where the registrant fails to agree to comply with the data requirements in either TABLE A for that use pattern, or TABLE B.

2. Precautionary Statements

Labels for all MP products containing Fenaminosulf must bear statements reflecting the acute human toxicity of the compound. Fenaminosulf is tentatively placed in Toxicity Category I for dermal toxicity effects, and Category II for acute oral and acute inhalation toxicity effects. Precautionary language requirements for eye irritation and skin irritation is dependent upon submission of data. The required precautionary statements associated with Toxicity Category I and II are specified in 40 CFR §162.10.

The following environmental hazard statement must appear on the manufacturing-use product labels:

"This pesticide is toxic to wildlife. Do not discharge into lakes, streams, ponds or public waters unless in accordance with a NPDES permit. For guidance, contact your Regional Office of EPA." The Agency may impose additional label requirements after the receipt and review of the data to be submitted under this Standard.

H. TOLERANCE REASSESSMENT

As stated previously in the Standard, no tolerances have been established for Fenaminosulf residues in or on any crop, or animal product. When Fenaminosulf was first registered, seed treatments were considered non-food uses. Presently seed treatments require tolerances unless adequate data is submitted to conclude there is no uptake of Fenaminosulf or its' degradates by the plant.

Registrants with Products Containing Fenaminosulf as the Active Ingredient

869 Green Light Company
P. O. Box 17985
San Antonio, TX 78217

-99 Green Light Bulb & Bedding Plant Food 4-12-12 with Fungicide
Type: 31 Fungicide
77 Unclassified
Form: 04 Granular

Ingredients:

034201 .4000 P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 2

2169 Patterson Chemical Co., Inc.
1400 Union Avenue
Kansas City, MO 64101

-173 Patterson's Root & Crown Rot Control
Type: 31 Fungicide
Form: 15 Soluble Concentrate

Ingredients:

034201 5.000 P-(Dimethylamino) Benzenediazo Sodium Sulfonate

056502 64.000 Pentachloronitrobenzene

Toxicity Category: 6

2749 Aceto Chemical Company
Agriculture Division
126-02 Northern Blvd.
Flushing, NY 11368

-226 Dimethylamino Benzene Diazo Sodium Sulfonate 35W
Turf and Soil Fungicide
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201 35.000 P-(Dimethylamino) Benzenediazo
Sodium Sulfonate
Toxicity Category: 2

3125 Mobay Chemical Corporation
Agricultural Chemicals
P. O. Box 4913
Kansas City, MO 64120

-65 Dexon Technical (Bayer 22555)
Type: 31 Fungicide
Form: 01 Technical Chemical

Ingredients:

034201 80.00 P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 2

-69 Dexon 70% Wettable Powder
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201 70.00 P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 2

-70 Dexon - Terraclor 35-35 Wettable Powder
Type: 31 Fungicide
77 Unclassified
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201 35.00 P-(Dimethylamino) Benzenediazo Sodium Sulfonate
056502 35.00 Pentachloronitrobenzene

Toxicity Category: 2

3125 (cont.)
Mobay Chemical Corporation
Agricultural Chemicals
P. O. Box 4913
Kansas City, MO 64120

-109 Dexon - Terraclor 5-5 Granular Soil Fungicide
Type: 31 Fungicide
77 Unclassified
Form: 04 Granular

Ingredients:

034201	5.00	P-(Dimethylamino) Benzenediazo Sodium Sulfonate
056502	5.00	Pentachloronitrobenzene

Toxicity Category: 3

-110 Dexon 5% Granular Soil Fungicide
Type: 31 Fungicide
Form: 04 Granular

Ingredients:

034201	5.0	P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 3

3125 (cont.) Mobay Chemical Corporation
Agricultural Chemicals
P. O. Box 4913
Kansas City, MO 64120

-145 Dexon Terraclor 2.5%-10% Dust
Type: 31 Fungicide
Form: 03 Dust

Ingredients:

034201	2.5	P-(Dimethylamino) Benzenediazo Sodium Sulfonate
056502	10.0	Pentachloronitrobenzene

Toxicity Category: 3

-154 Dexon 35% Wettable Powder Turf & Soil Fungicide
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201	35.0	P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 2

3125 (cont.)
Mobay Chemical Corporation
Agricultural Chemicals
P. O. Box 4913
Kansas City, MO 64120

-287 Dexon D 72% Wettable Powder in Water Soluble Packets
Type: 31 Fungicide
77 Unclassified
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201	32.0	P-(Dimethylamino) Benzenediazo Sodium Sulfonate
081901	40.0	Chlorothalonil (Tetrachloro-isophthalonitrile)

Toxicity Category: 1

-298 Dexon D 72% Wettable Powder
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201	32.0	P-(Dimethylamino) Benzenediazo Sodium Sulfonate
081901	41.0	Chlorothalonil (Tetrachloro-isophthalonitrile)

Toxicity Category: 1

-303 Dexon 70% Wettable Powder Seed and Soil Fungicide
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201	70.0	P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 2

5967 Moyer Chemical Company
Box 945
San Jose, CA 95108

-55 Dexaclor 35-35
Type: 31 Fungicide
Form: 06 Wettable Powder (WP or W)

Ingredients:

034201	35.00	P-(Dimethylamino) Benzenediazo Sodium Sulfonate
056502	35.00	Pentachloronitrobenzene

Toxicity Category: 2

8278 Metro Biological Lab
8241 Gay Street
Cyphers, CA 9063908

99247 Metro (Tested) Granular Fungicide
Type: 18 Intrastate
31 Fungicide
Form: 04 Granular

Ingredients:

034201 5.00 P-(Dimethylamino) Benzenediazo Sodium Sulfonate

Toxicity Category: 3

State Registration of a Pesticide to Meet a Special Local Need [24(c)]

SLN Number	Reg. Number	Applicant
CA80-0117	3125-154	Kern County Agric. Commissioner P. O. Box 1351 Bakersfield, CA 93302

Product Name: Dexon 35% Wettable Powder Turf & Soil Fungicide
Type: 31 Fungicide
Form: 06 Wettable Powder

Active Ingredients:

034201 35.00% P-(Dimethylamino) Benzenediazo
Sodium Sulfonate

Site: 3408916010 Lilac (Cuttings)

Pest: FZZZPCN010 Phytophthora

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted 2/. Any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 3/, or data collected under the approved protocols of the Organization for Economic Cooperation

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ USEPA, 1982. Pesticide Registration; Proposed Data Requirements Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192)

3/ USEPA, 1983. Pesticide Assessment Guidelines, National Technical Information Service, Springfield, VA.

and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants

(Footnote continued at bottom of next page)

(Footnote continued from bottom of previous page)

is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF[1]

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (All data must be submitted for each MP)				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	GS-000126051	No
61-2 - Statement of Composition	TGAI	Partially	GS-000126051	Yes
61-3 - Discussion of Formation of Ingredients	TGAI	No	—	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No	—	Yes
62-2 - Certification of Limits	TGAI	Partially	GS-000126051	Yes
62-3 - Analytical Methods for Enforcement of Limits	TGAI	No	—	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No	—	Yes
63-3 - Physical State	TGAI	Yes	GS-000126052	No
63-4 - Odor	TGAI	No	—	Yes
63-5 - Melting Point	TGAI	No	—	Yes
63-6 - Boiling Point	N/A[4]	N/A	—	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	—	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF[1]

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	No	—	Yes
63- 9 - Vapor Pressure	PAI	No	—	Yes
63-10 - Dissociation constant	PAI	No	—	Yes
63-11 - Octanol/water partition coefficient	PAI	No	—	Yes
63-12 - pH	TGAI	No	—	Yes
63-13 - Stability	TGAI	Yes	GS-000126052	No
Other Requirements:				
64- 1 - Submittal of samples	N/A	N/A	—	No

[1]The 80% technical (T) also serves as a manufacturing-use product.
[2]Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[3]Data must be submitted no later than 6 months from the date of this Standard.
[4]Not required because the 80% technical is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data to Satisfy this Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	No	—	Yes
- Livestock	PAIRA	No	—	Yes
171-4 - Residue Analytical Method				
- Plant residues	Parent compound and/or possible metabolites	No	—	Yes3
- Animal residues	Parent compound and/or possible metabolites	No	—	Yes3
171-4 - Storage Stability Data	PAI	No	—	Yes3
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Root and Tuber Vegetables Group	EP	No	—	No4
Sugar beets				
--Crop field trials	TEP	No	—	Yes3
--Processed Food/Feed	EP	No	—	Yes3
Table beets				
--Crop field trials	TEP	No	—	Yes3
--Processed Food/Feed	EP	No	—	Yes3

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Leaves of Root and Tuber Vegetables Group	EP	No	—	No[4]
Sugar beet tops				
--Crop field trials	TEP	No	--	Yes[3]
--Processed Food/Feed	EP	No	--	Yes[3]
Table beet tops				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
- Leafy Vegetables (except Brassica Vegetables) Group	EP	No	—	No[4]
Spinach				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yew[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Legume Vegetables (Succulent or Dried) Group	EP	No	—	No[4]
Lima beans				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Peas				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Snap beans				
-- Crop field trials	TEP	No	—	Yes[3]
-- Processed Food/Feed	EP	No	—	Yes[3]
- Foliage of Legume Vegetables Group	EP	No	—	No[4]
Lima bean forage and hay				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR PENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Foliage of Legume Vegetables Group (continued)				
Pea forage and hay				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Snap bean forage and hay				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
- Fruiting Vegetables (Cucurbits) Group	EP	No	—	No[4]
Cucumbers				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Cereal Grains Group	EP	No	—	No[4]
Corn				
--Crop trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Sorghum				
--Crop trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
- Forage, Fodder, and Straw of Cereal Grains Group	EP	No	—	No[4]
Corn forage and fodder				
--Crop trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Sorghum forage and fodder				
--Crop trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Miscellaneous Commodities Group				
Avacados				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Cottonseed				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Pineapple				
--Crop field trials	TEP	No	--	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]
Sugarcane				
--Crop field trials	TEP	No	—	Yes[3]
--Processed Food/Feed	EP	No	—	Yes[3]

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Potable Water	EP	No	—	No[4]
- Fish	EP	No	—	No[4]
- Irrigated Crops	EP	No	—	No[4]
— Field trials	EP	No	—	No[4]
-- Processed Food/Feed	EP	No	—	No[4]
- Food Handling	EP	No	—	No[4]
- Meat/milk/poultry/eggs	TGAI or plant metabolites	No	—	Yes[3]

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; EP = End-use product; TEP = Typical end-use product; PAIRA = Pure active ingredient, radiolabelled.
2/ Data must be submitted no later than 6 months from the date of this Standard.
3/ Requirement will be based on the residues of concern present as determined by the C^{14} studies.
4/ No registered uses indicated on labeling.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 7/	Use Pattern 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D	No	—	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	B,D	No	—	Yes
161-3 - On soil	TGAI or PAIRA	D	No	—	Yes
161-4 - In Air	—	N/A	—	—	—
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,C,D	No	—	Yes
162-2 - Anaerobic Soil	—	N/A	—	—	—
162-3 - Anaerobic Aquatic	—	N/A	—	—	—
162-4 - Aerobic Aquatic	—	N/A	—	—	—
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D A,C	partially 5/ No	✓ 00068214 —	Yes Yes
163-2 - Volatility (Lab)	TEP	C	No	—	2/
163-3 - Volatility (Field)	TEP	C,D	No	—	3/

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 7/	Use Pattern 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,D	No	—	Yes
164-2 - Aquatic (Sediment)	—	N/A	—	—	—
164-3 - Forestry	—	N/A	—	—	—
164-4 - Combination and Tank Mixes	—	N/A	—	—	—
164-5 - Soil, Long-term	TEP	D	No	—	4/
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	—	N/A	—	—	—
165-2 - Rotational Crops (Field)	—	N/A	—	—	—
165-3 - Irrigated Crops	—	N/A	—	—	—
165-4 - In Fish	TGAI or PAIRA	B,D	No	—	Yes
165-5 - In Aquatic Non-Target Organisms	—	N/A	—	—	—

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 7/	Use Pattern 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?

1) A = Domestic outdoor = lawns
   B = Terrestrial, non-food = ornamental turf and soil drench
   C = Greenhouse, non-food = ornamentals only
   D = Terrestrial, food = seed and seedpiece treatment, avocados (orchard trees, fruit and nuts).
2) To assess the need for lab test of volatility, the following data are required: 1) vapor pressure, soil absorption (Kd), and water solubility (@ 25°C) of the active ingredient.
3) Depends on the results of the Lab test for volatility.
4) Depends on aerobic soil metabolism and soil dissipation: Required if residues from soil dissipation do not reach 50%, or if the total residue (excluding bound) in aerobic soil metabolism are greater than 50% prior to subsequent recommended application.
5) Aged (aerobic soil) 30 days samples must be tested by either 1) extracts from the samples or, 2) the aged soil samples must be tested
6) Foliar applied to lawns and turf
7) Composition: TGAI = technical grade active ingredient; PAIRA = pure active ingredient radio labeled; TEP = typical end-use product

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,C,D	Partially	00091267[5],00091266[6]	Yes
81-2 - Dermal LD_{50}	TGAI	A,B,C,D	Partially	00091263[8],00091266[9] 00091267[10]	Yes
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,C,D	Partially	00091263[11],00091269[12]	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	—	—	—
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B,C,D	Partially (rodent)	00091271[13]	No
82-2 - 21-Day Dermal	TGAI	A,B,C,D	No	—	Yes
82-3 - 90-Day Dermal	TGAI	N/A	—	—	—
82-4 - 90-Day Inhalation - Rat	TGAI	N/A	—	—	—
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	N/A	—	—	—

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,C,D	Partially	00091273[15],00091272[14]	Yes
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B,C,D	Partially	00091264[7],GS000126-001[18]	Yes
83-3 - Teratogenicity - 2 species	TGAI	A,B,C,D	No	—	Yes
83-4 - Reproduction, 2-generation	TGAI	A,B,C,D	No	—	Yes
MUTAGENICITY TESTING					
84-2 - Gene Mutation[4]	TGAI	A,B,C,D	Partially[19]	GS-000126008,GS-000126003 GS-000126004	Yes[4]
84-2 - Chromosomal Aberration[4]	TGAI	A,B,C,D	Partially[19]	GS-000126005,GS-000126007	Yes[4]
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,C,D	Yes	GS-000126007,GS-000126004	No

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B,C,D	Partially	00091265[17],00091264[16]	Yes
85-2 - Domestic Animal Safety	--	N/A	--	--	--

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, non-food; C = Domestic outdoor; D = Greenhouse, non-food.
3/ Data must be submitted no later than 6 months after issuance of standard for the acute, subchronic and mutagenicity studies. 48 months for chronic studies.
4/ Additional mutagencity testing may be required, depending upon results of these required studies.
5/ Source of animals, housing, feeding conditions, rats/dose level, # of dose levels, purity of compound, toxic symptoms - not reported.
6/ Dose levels, rats/dose level - not reported.
7/ Deficient in experimental design, execution, and reporting of data.
8/ Data reported insufficient.
9/ Site of application, exposure time, sex and number of animals and other experimental details - not reported.
10/ # of animals, exposure and observation times, application site and its area, if the site was occluded and then washed after the termination of exposure - not reported.
11/ Deficient in experimental design.
12/ Deficient in experimental design and execution of study.
13/ Deficient in experimental design.
14/ Deficient in planning of the study, experimental procedure,and reporting of data.
15/ Deficient in experimental protocol and reported data.
16/ # of animals used/dose level, sex, route of administration - not reported.
17/ Experimental details omitted.
18/ Poor design and execution, technical material must be used.
19/ Cited studies are acceptable, but additional studies are needed to fulfill requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	2/	No	--	No
132-1 - Soil Dissipation	TEP	2/	No	--	No
133-3 - Dermal Exposure	TEP	2/	No	--	No
133-4 - Inhalation Exposure	TEP	2/	No	--	No

1/ Composition: TEP = Typical end-use product.
2/ Foliar applied to lawns and turf.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	ABFH	Yes	00097678	No
71-2 - Avian Dietary LC_{50}					
Waterfowl	TGAI	BFH	Yes	00097677	No
Upland Game	TGAI	BFH	Partially	00048109	Yes 4
71-3 - Wild Mammal Toxicity	TGAI	AB	No	—	No 5
71-4 - Avian Reproduction	TGAI	AB	No	—	No 5
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	AB	No	—	No 5
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}					
Coldwater	TGAI	ABFH	Yes	GS-0003503	No
Warmwater	TGAI	ABFH	Yes	GS-0003503	No
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	ABFH	No	—	Yes
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	AB	No	—	No 5
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	AB	No	—	No 5

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI	AB	No	--	No 5
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	AB	No	--	No 5
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	AB	No	--	No 5

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than 6 months after issuance of the Standard.
4/ One second test on an upland game bird is required provided missing information such as % a.i. and # of test Birds is not submitted or is inappropriate.
5/ Not normally required - decided on a case by case basis.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP	A,B,C,D	No	-	No 4/
NONTARGET AREA PHYTOTOXICITY TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D	No	-	No 4/
122-1 - Vegetative Vigor	TGAI	A,B,C,D	No	-	No 4/
122-2 - Aquatic Plant Growth TIER II	TGAI	A,B,C,D	No	-	No 4/
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D	No	-	No 4/
123-1 - Vegetative Vigor	TGAI	A,B,C,D	No	-	No 4/
123-2 - Aquatic Plant Growth TIER III	TGAI	A,B,C,D	No	-	No 4/
124-1 - Terrestrial Field	TEP	A,B,C,D	No	-	No 4/
124-2 - Aquatic Field	TEP	A,B,C,D	No	-	No 4/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Greenhouse, Non-Food; D=Domestic Outdoor.
3/ Data must be submitted no later than 6 months after issuance of the Standard.
4/ These requirements are generally waived unless it is believed there is a phototoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	B	Yes	00028772	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	B	No[4]	--	No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	B	No[5]	--	No
141-4 - Honey bee subacute feeding study	(Reserved)[6]/	--	--	--	--
141-5 - Field testing for pollinators	TEP	B	No	--	No

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMINOSULF

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) 7/				
142-2 - Aquatic insect life-cycle study	(Reserved) 7/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 7/				
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3	(Reserved) 7/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: B=Terrestrial, Non-Food.
4/ As pesticide tested low in toxicity in first level test, no further testing is required
5/ Required only for pesticides intended for foliar application to seed alfalfa
6/ Reserved pending development of test methodology
7/ Reserved pending decision as to whether the data requirement should be established

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENAMINOSULF

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Yes	GS-000126051	No
61-2 - Statement of Composition	MP	Partially[4]	GS-000126051	Yes
61-3 - Discussion of Formation of Ingredients	MP	No	—	Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	No	—	Yes
62-2 - Certification of Limits	MP	Partially[4]	GS-000126051	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	No	—	Yes
Physical and Chemical Characteristics				
63-2 - Color	MP	No	—	Yes
63-3 - Physical State	MP	Yes	GS-000126052	No
63-4 - Odor	MP	No	—	Yes
63-7 - Density, bulk density, or specific gravity	MP	No	—	Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENAMINOSULF

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	No	—	Yes
63-14 - Oxidizing or reducing action	MP	No	—	Yes
63-15 - Flammability	MP	No	—	Yes
63-16 - Explodability	MP	No	—	Yes
63-17 - Storage Stability	MP	No	—	Yes
63-18 - Viscosity	MP	N/A	—	No
63-19 - Miscibility	MP	N/A	—	No
Other Requirements				
64- 1 - Submittal of Samples	MP	N/A	—	No

[1]Composition: MP = Manufacturing-use product.
[2]Data must be submitted no later than 6-8 months from the date of this Standard.
[3]Not required because the product is solid at room temperature.
[4]Data must be submitted for each product.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENAMINOSULF

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Partially	00091267[3], 00091266[4]	Yes
81-2 - Dermal LD_{50}	MP	Partially	00091263[5], 00091266[6] 00091267[7]	Yes
81-3 - Inhalation LC_{50} - Rat	MP	Partially	00091263[8], 00091269[9]	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No	--	Yes
81-5 - Primary Dermal Irritation	MP	No	--	Yes
81-6 - Dermal Sensitization	MP	No	--	Yes

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than 6 months after issuance of the Standard.
3/ Source of animals, housing/feeding conditions, rats/dose level, # of dose levels, purity of compound, toxic symptoms - not reported.
4/ Dose levels, rats/dose level - not reported.
5/ Data reported insufficient.
6/ Site of application, exposure time, sex and # of animals - not reported.
7/ # of animals, exposure and observation times, application site and its area, if the site was occluded and then washed after the termination of exposure - not reported.
8/ Deficient in experimental design.
9/ Deficient in experimental design and execution of study.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address,

or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to

protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. Henry M. Jacoby
Product Manager 21
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1900

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn

followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

Registration Standard Bibliography for Fenaminosulf. Citations are considered to be part of the data base supporting registration under the Standard.

00028772 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1973) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. Rev. By Univ. of California--Riverside, Dept. of Entomology. Riverside, Calif.: UC, Agricultural Extension Service. (Also In unpublished submission received Apr 2, 1980 under 464-556; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242149-Z)

00048109 Dewitt, J.B.; Stickel, W.H.; Springer, P.F. (1962) Wildlife Studies, Patuxent Wildlife Research Center: 1961-1962. (U.S. Fish and Wildlife Service, unpublished study; CDL:241577-A)

00068214 Thornton, J.S.; Hurley, J.B.; Obrist, J.J. (1976) Soil Thin-layer Mobility of Twenty Four Pesticide Chemicals: Report No. 51016. (Unpublished study received Jul 11, 1977 under 3125-315; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:230908-I)

00091263 Kimmerle, J. (1958) Substance 22555: Submitter Report No. 2266. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Farbenfabriken Bayer, West Germany, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-C)

00091264 Herrmann, R.G.; DuBois, K.P. (1949) Studies on the toxicity and pharmacological action of p-dimethylaminobenzenediazo sodium sulfonate (DAS). Journal of Pharmacology and Experimental Therapeutics 95(2):262-271. (Submitter 2307; also In unpublished submission received Nov 12, 1967 under 7F0613; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-D)

00091265 Herrmann, R.G.; DuBois, K.P. (1949) The effect of p-dimethylaminobenzenediazo sodium sulfonate (DAS) on the enzymatic reactions of intermediary carbohydrate metabolism. Journal of Pharmacology and Experimental Therapeutics 95(2):272-284. (Submitter 2308; also In unpublished submission received Nov 12, 1967 under 7F0613; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-E)

00091266 DuBois, K.P.; Schmalgemeier, D. (1958) The Acute Toxicity of Bayer 22555 to Experimental Animals: Submitter 2656. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Dept. of Pharmacology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-F)

00091267 DuBois, K.P.; Schmalgemeier, D. (1959) The Acute Toxicity of Recrystallized and Technical Bayer 22555: Submitter 3525. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Dept. of Pharmacology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-G)

00091269 Doull, J.; DuBois, K.P. (1959) Studies on the Acute Inhalation Toxicity of Bayer 22555: Submitter 3657. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Dept. of Pharmacology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-I)

00091271 DuBois, K.P.; Vaughn, J.; Doull, J. (1959) The Effect of Diets Containing Bayer 22555 on Rats: Submitter 3962. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Dept. of Pharmacology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-K)

00091272 Doull, J.; Vesselinovitch, D.; Fitch, F.; et al. (1963) Chronic Oral Toxicity of Dexon to Male and Female Rats: Submitter 20073. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Depts. of Pharmacology and Pathology, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090799-L)

00091273 Doull, J.; Vesselinovitch, D.; Fitch, F.; et al. (1963) Chronic Oral Toxicity of Dexon to Male and Female Dogs: Submitter 20074. (Unpublished study received Nov 12, 1967 under 7F0613; prepared by Univ. of Chicago, Depts. of Pharmacology and Pathology; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 090799-M)

00097677 Lamb, D.W.; Jones, R.E. (1974) Dietary Toxicity of (R) Dexon Technical to Mallard Ducks: Report No. 39229. (Unpublished study received Feb 27, 1974 under 3125-65; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:129192-A)

00097678 Lamb, D.W.; Jones, R.E. (1973) Acute Oral Toxicity of (R) Dexon Technical to Mallard Ducks: Report No. 38926. (Unpublished study received Feb 27, 1974 under 3125-65; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:129192-B)

GS-000126001 U.S. Department of Health, Education, and Welfare. 1978. Bioassay of Formulated Penaminosulf for Possible Carcinogenicity. DHEW Pub. No. (NIH) 78-1351.

GS-000126003 Shirasu, Y., et.al. 1976. Mutagenicity Screening of Pesticides in the Microbial System. Mutation Research 40:p.19-30.

GS-000126004 Kadu, T., et.al. 1974. Screening of Pesticides for DNA Interactons by 'REC-ASSAY' and Mutagenesis Testing and Frameshift Mutagens Detected. Mutation Research 26:p.243-248.

GS-000126005 Zutshi, U., and B.L. Kaul. 1975. Studies on the Cytogenetic Activity of some common Fungicides in higher plants. Cytobios 12:p.61-67.

GS-000126007 Vigfusson, N.V. and E.R. Vyse. 1980. The effect of the pesticides Dexon, Captan, and Round-up on sister-chromatid exchanges in human lymphocytes in vitro. Mutation Research 79:p.53-57.

GS-000126008 Rogers, S.J., et.al. 1978. Mutagenicity of the fungicide Dexon. Mutation Research 53:p.91.

GS-000126051 Bayer, A.G. 1968. Confidential Statement of Formula for E.P.A. Registration No. 3125-154. Mobay Chemical Corporation.

GS-000126052 Martin, H. and C.B. Worthing (ed.) 1974. Pesticide Manual: Basic information on the Chemical Used as active components of Pesticides. 4th Edition. London 265p.

GS-0003503 Johnson, W.W. and M.T. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. U.S. Dept. of Interior. Fish and Wildlife Service Resource Publication No. 137.

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

3. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "P" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alconol
Lead acetate
Lindane
Maleic hydraride
Mercury
Methyl alconol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Napnthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphoroditnioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Maleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

Mobay Chemical Corporation
Agricultural Chemicals Division
P. O. Box 4913
Kansas City, MO 64120

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Fenaminosulf as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the

steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Mr. Henry M. Jacoby
Product Manager 21
Environmental Protection Agency
Registration Division (TS-767)
Office of Pesticide Programs
Washington, D.C. 20460
Telephone 703/557-1900

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Reg. No.	Product Name
3125-65	Dexon Technical

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT FENAMINOSULF

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

EPA Reg. No.	Co. Name & Address	% Active Ingredient	Formulation Type
3125-65	Mobay Chemical Co. Agricultural Chemicals Div. P. O. Box 4913 Kansas City, MO 64120	80.0%	TP
3125-69	"	70.0%	WP
3125-70	"	35.0%	WP
3125-109	"	5.0%	G
3125-110	"	5.0%	G
3125-145	"	2.5%	D
3125-154	"	35.0%	WP
3125-287	"	32.0%	WP
3125-298	"	32.0%	WP
3125-303	"	70.0%	WP
5967-55	Moyer Chemical Co. 1310 Bayshore Highway P. O. Box 945 San Jose, CA	35.0%	WP
869-99	Green Light Plant Food Co. San Antonio, TX 78209	0.4%	G
2169-173	Patterson Chemical Co. 1400 Union Avenue Kansas City, MO 64101	5.0%	WP
2749-226	Aceto Chemical Co., Inc. 126-02 Northern Blvd. Flushing, NY 11368	35.0%	WP
8278-9247	Metro Biological Lab. 8241 Gay St. Cypress, CA 90639	5.0%	G